

## **REMARKS**

### **Introduction**

Claims 1, 9, 17, 20, 23, 25 and 27-29 have been amended. The application continues to include claims 1-29.

Applicants acknowledge that claims 9 and 29 would be allowable if rewritten in independent form. In response, claims 9 and 29 have been rewritten. However, reconsideration of the rejection of the entire application is respectfully requested in view of the above amendment and the following remarks.

### **The Claims are Allowable over the Prior Art Because the Prior Art Fails to Disclose a Screw Having a Channel that Receives a Ball Collet with an Integral Yoke Portion and Threaded Insertion Portion**

Claims 1, 5-6, 8, 15, 16, 18 and 23-24 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tatar (U.S. Pat. No. 5,910,142). Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatar in view of Doubler et al. (U.S. Pub. No. 2005/0070899). Claims 4, 7 and 8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatar in view of Brace et al. (U.S. Pat. No. 6,187,005). Claims 12-16, 20-22 and 25-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatar in view of Ferree (U.S. Pat. No. 6,802,844). Claims 10-11 and 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatar in view of Gearin (U.S. Pat. No. 3,530,548). Claims 17-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatar in view of Gearin (U.S. Pat. No. 3,530,548).

Finally, claims 27 and 28 are rejected under 35 U.S.C. § 102(b) as being anticipated by Griss (U.S. Pat. No. 5,910,142).

Reconsideration of these rejections is respectfully requested because the prior art fails to disclose a screw having a channel that receives a ball collet with an integral yoke portion and threaded insertion portion in which the channel is fixed relative to the threaded insertion portion.

One embodiment of the present invention is a pedicle screw assembly that includes a pedicle screw 100. The head or yoke portion 104 of screw 100 includes a plurality of threaded posts 106a, 106b that define a cylindrical channel 108. A ball collet 200 is seated directly in channel 108 when the assembly is in an assembled state. Because channel 108 is formed on screw 100, screw 100 is a one-piece design, which is advantageous.

Tatar discloses a pedicle screw assembly which includes a screw 100 having a head 104 that includes a recess 110 (col. 5, ll. 1-8). However, recess 110 is not designed for receiving a ball or ferrule 130. Rather, "[t]he recess 110 is bifunctional insofar as it includes a slot 112 or other suitable screw driving tool receiving conformation as well as a curvately concave circumferential lip 114" (col. 5, ll. 8-11).

Unlike the present invention, the assembly of Tatar further includes a separate body element 120. Body element 120 includes a channel 123 that receives a rod 150 and ferrule 130 (col. 5, ll. 13-18). Body element 120 is placed over head 104 of screw 100, but is a separate piece from screw 100, and is even able to rotate relative to screw 100:

The bottom opening 128 of the axial bore 122 is larger than the shaft 102 of the screw 100, but is less than the diameter of the head 104, so that the head can be nested in the socket 126 at the bottom of the bore 122, with the undersurface 106 of the head 104 slidably (initially) nested against the tapered interior surface 126. The corresponding geometries

permit ***the screw 100 to polyaxially rotate relative to the body 120*** without disrupting the overall nesting of the head 104 in the socket 126.

(col. 5, ll. 27, 34, emphasis added).

Griss discloses a system for osteosyntheses at the vertebral column. Griss discloses a retaining means 12 (Figs. 2 and 8) with a tuning-fork-like head 15 and two limbs 16 (col. 8, l. 56 – col. 2, l. 2). Griss discloses that a U-shaped receptacle 18, which is received within limbs 16, receives a connecting element 14 (col. 9, ll. 2-7). Griss further discloses that “[t]he floor 22 of the receptacle 18 is approximately concave, according to FIGS. 2 and 8, to correspond to a swivel-bearing element 23 disposed between the floor 22 of the receptacle 18 and the connecting element 14. The bearing surface 24 of the swivel-bearing element 23, which faces the floor 22 of the receptacle 18, has a complementary convex shape.” Col. 9, ll. 12-18). Therefore, unlike the present invention, the ball or “swivel-bearing element 23” does not sit directly within a channel that is formed integral to the screw and that does not move relative to a threaded insertion portion of the screw. Instead, in Griss the swivel-bearing element 23 that receives the ball can move relative to the screw.

In contrast to Tatar and the other cited prior art, independent claim 1 recites a pedicle screw wherein “said pedicle screw comprises an **integral** threaded insertion portion and yoke portion, and said yoke portion comprises said threaded posts; and wherein **said threaded posts are fixed relative to said threaded insertion portion.**” For at least these reasons, claim 1 should now be allowable over Tater.

Independent claims 17, 20, 23 and 25 include similar limitations as claim 1. Based at least on the foregoing, these claims should also be allowable over Tater.

Further, in contrast to Griss and the other cited prior art, independent claim 27 recites a pedicle screw “defining a substantially cylindrical channel for **seating a ball collet**” wherein “said pedicle screw comprises an **integral** threaded insertion portion and yoke portion, and said yoke portion comprises said threaded posts; and wherein **said threaded posts are fixed relative to said threaded insertion portion**”. For at least these reasons, claim 27 should now be allowable over Griss.

The remaining claims each depend from one of the above independent claims, and therefore should also be allowable based at least on the foregoing reasons.

### **Conclusion**


Applicants respectfully request favorable action in connection with this application.

The Examiner is invited and urged to contact the undersigned to discuss any matter concerning this application.

No fee is believed to be due for this submission. Should a fee be required, the Commissioner is authorized to charge any such fee to Womble Carlyle's Deposit Account No. 09-5028.

Respectfully Submitted,

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